

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

GENETICS & IVF INSTITUTE,)	
)	
Plaintiff,)	
)	
v.)	1:10cv996(JCC/TRJ)
)	
DAVID KAPPOS,)	
Under Secretary of Commerce)	
for Intellectual Property and)	
Director of the U.S. Patent)	
and Trademark Office, et al.,)	
)	
Defendants.)	

M E M O R A N D U M O P I N I O N

This matter is before the Court on the parties' cross-motions for summary judgment. For the following reasons, the Court will deny Plaintiff's motion, [Dkt. 13], and will grant Defendants' motion, [Dkt. 15].

I. Background

A. The Parties and the Case

Plaintiff Genetics & IVF Institute ("Plaintiff" or "GIVF") brings this action against defendants the United States Patent and Trademark Office (the "USPTO") and David Kappos, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the USPTO (together with the USPTO, "Defendants"). Under the Administrative Procedure Act, 5 U.S.C. §§ 551-706 (the "APA"), Plaintiff seeks to set

aside the denial of an application made under the Drug Price Competition and Patent Term Restoration Act, popularly known as the "Hatch-Waxman Act," Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984), to extend the term of a U.S. patent, as further described below. (Complaint ("Compl.") [Dkt. 1] ¶ 1.)

B. Overview of Relevant Patent Law

Under the Patent Act, 35 U.S.C. § 100 *et seq.* (the "Patent Act"), a United States patent expires after a certain term, generally 20 years from the date on which the patent application was filed. See 35 U.S.C. § 154(a)(2). For patents claiming certain drug and medical devices, some or all of the patent term may be consumed by the (often lengthy) Food and Drug Administration ("FDA") approval process for products utilizing that patent. See 35 U.S.C. § 156; 21 U.S.C. § 355(a).

Recognizing this, the Hatch-Waxman Act provides patent holders with "interim" extensions for patents utilized by products that remain under FDA review when the relevant patent term is set to expire. These extensions, however, are not automatic. The first time a patent holder seeks an interim patent term extension (an "Extension"), the relevant statute, 35 U.S.C. § 156(d)(5)(A), provides that the holder must file an application with the USPTO "during the period beginning [six] months, and ending 15 days, before [the patent term] is due to expire." Then, "[i]f the [USPTO] Director determines that,

except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section . . . [the Director] shall issue to the applicant a certificate of interim extension" for a maximum length of one year. 35 U.S.C. § 156(d)(5)(B).

Patent law permits patent holders to apply for additional, "subsequent," Extensions. On that front, the statute provides that

[t]he owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. *Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.*

35 U.S.C. § 156(d)(5)(C) (emphasis added). It is this statute, particularly the emphasized language, which is relevant here.

C. Factual Background

i. The '759 Patent

On August 4, 1992, the USPTO issued U.S. Patent No. 5,135,759 (the "'759 Patent") to the United States Department of Agriculture ("USDA"). (Plaintiff's Memorandum in Support ("P. Mem.") [Dkt. 14] at 3.) The '759 Patent is entitled a "Method to Preselect the Sex of Offspring" and claimed a method of preselecting the sex of offspring by sorting sperm into X and Y

chromosome bearing sperm. (Defendants' Memorandum in Support ("D. Mem.") [Dkt. 16] at 7.)

The USDA and GIVF entered into a private agreement under which the USDA granted GIVF an exclusive license to obtain regulatory approval for products created under the '759 Patent and to market any such products in the United States. (P. Mem. at 3.) GIVF has applied to the FDA for approval of products under the '759 Patent and has commenced clinical studies. *Id.* GIVF has not yet received FDA approval. *Id.*

ii. The 2009 Extension

The '759 Patent was set to expire on August 4, 2009. *Id.* Because GIVF had not received FDA approval, the USDA timely filed, on June 5, 2009, an application with the USPTO for a first Extension. (D. Mem. at 7.) On July 28, 2009, the USPTO granted the first Extension, thereby extending the term of the '759 Patent for one year, to August 4, 2010. *Id.* The order granting the Extension was published in the Federal Register on August 4, 2009. *Id.*

iii. The 2010 Extension

As of July 2010, the GIVF's FDA application was still pending. (P. Mem. at 4.) With the '759 Patent set to expire on August 4, 2010, the USDA filed a request for a second Extension with the USPTO on July 27, 2010. *Id.*

Under 35 U.S.C. § 156(d)(5)(C), however, the request for the second Extension was due on *July 6, 2010*, so the USDA's application was untimely. *Id.* GIVF was responsible for drafting the second Extension application and engaged counsel to do so. (D. Mem. at 8.) "On or about" July 19, 2010, GIVF's counsel discovered that the application was due on July 6. (P. Mem. at 4.)

GIVF's counsel used a computer program to track patent-filing dates, and the program did not provide a reminder that the application for the second Extension was due. (D. Mem. at 8.) The program's failure was not a malfunction, however; the program was not capable of tracking filing dates for Extension applications, though GIVF's counsel was unaware that the program lacked this capability. *Id.*

Along with its July 27, 2010 application for a second Extension, the USDA petitioned the USPTO, pursuant to 37 C.F.R §§ 1.182 and 1.183, for a suspension of the applicable USPTO rule. (P. Mem. at 4.)

iv. Effect of the Late Application

On August 2, 2010, the USPTO denied the USDA's petition and request for a second Extension. *Id.* The USPTO deemed this denial a final agency action under the APA. *Id.* On August 4, 2010, the '759 Patent expired. *Id.*

D. Agency Review

Plaintiff claims that the USPTO's decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (Compl. ¶ 37 (quoting 5 U.S.C. § 706(2)(A))). Because this is a review under the APA of the USPTO's decision denying the USDA's petition for a second Extension, a brief overview of the USPTO's decision is helpful.

The USPTO reasoned that, over fifteen years prior to the USDA's petition, it promulgated formal regulations that provided its interpretation that the timing provisions found in § 156(d)(5)(C) are mandatory. (D. Mem. at 10; Administrative Record ("AR") [Dkt. 11-2] at 90.)

The USPTO further found that "[a]ny analysis of a statute begins with the language of the statute itself" and that through the use of, and plain meaning of, "shall," Congress "indicate[d] an imperative duty." (D. Mem. at 10; AR at 89.) The USPTO also reasoned that since another provision of § 156, § 156(a), which dictates when the USPTO "shall" provide a patent holder with an Extension, like § 156(d)(5)(C) uses "shall," the term should be interpreted the same way in both instances. (D. Mem. at 10; AR at 91-92.)

The USPTO's decision also explained that the timing provisions for Extensions serve an important purpose, namely the "timely publication of the notice that a patent was being

extended based on the ongoing regulatory review of a product claimed by the patent." (D. Mem. at 10; AR at 93.) The USPTO also determined that because the Patent Act included various provisions that vested the USPTO with discretion to excuse errors, but did not include this discretion in § 156(d)(5)(C), "it speaks volumes that Congress provided no avenue to allow the USPTO to accept a late subsequent [Extension] application." (D. Mem. at 10; AR at 93.)

E. Procedural Background

Plaintiff filed this case on September 1, 2010. [Dkt. 1.] The parties filed an agreed order, entered by this Court, submitting the case to a decision based on the administrative record before the USPTO and the parties' cross dispositive motions, on the papers and without a hearing. [Dkt. 12.] Plaintiff filed its motion for summary judgment on April 13, 2011 [Dkt. 13], and Defendants filed their motion for summary judgment on May 5, 2011 [Dkt. 15]. Plaintiff replied on May 18, 2011 [Dkt. 17], and Defendants replied on May 27, 2011 [Dkt. 18]. The parties' motions are before the Court.

II. Standard of Review

"Under the APA, agency action may be set aside if the court finds that the agency action was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 343 (E.D.

Va. 2009) (quoting 5 U.S.C. § 706(2)(A)). Although this is an APA action, "the ordinary standard for summary judgment applies." *Tafas v. Dudas*, 541 F. Supp. 2d 805, 810 (E.D. Va. 2008) (vacated in part by *Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), rehearing *en banc* granted and opinion vacated by *Tafas v. Doll*, 328 F. App'x 658 (Fed. Cir. 2009) (citing *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005))). Under the "ordinary" and well-settled standard, summary judgment is appropriate only if the record shows "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); see also *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

On that "genuine issue of material fact" front, the APA "confines judicial review of executive branch decisions to the administrative record of proceedings before the pertinent agency." *Shipbuilders Council of Am. v. U.S. Dept. of Homeland Sec.*, --- F.Supp.2d ----, 2011 WL 938368, at *7 (E.D. Va. Mar. 17, 2011) (citing 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). "As such, there can be no genuine issue of material fact in an APA action, and the legal questions presented in [an APA] action are therefore ripe for resolution on cross-motions for summary judgment." *Id.* (citing *Am. Forest Res. Council v. Hall*, 533 F. Supp. 2d 84, 89 (D.D.C. 2008)

(quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)) ("[I]t is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas 'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'"). As the District of Columbia Circuit has stated, "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001).

Finally, it is worth noting that because Plaintiff invokes this Court's jurisdiction over its case under 28 U.S.C.A. § 1338, (Compl. ¶ 6), any appeal in this matter would be noticed to the Federal Circuit and not the Fourth Circuit.¹ See 28 U.S.C.A. § 1295; see also *Tafas*, 541 F. Supp. 2d at 811 n.3 ("[A]ppellate jurisdiction over this case lies in the U.S. Court of Appeals for the Federal Circuit, whose law governs the standard applied at summary judgment.") (citing *Star Fruits*, 393 F.3d at 1281). "In patent-related cases filed in the Eastern District of Virginia, Federal Circuit law governs substantive issues, and the law of the Fourth Circuit applies to procedural

¹ Only Defendants discussed the applicability of Federal Circuit law as opposed to Fourth Circuit law, and Plaintiff did not contest this point in its Reply.

matters that are not unique to patent law.”² *Level 3 Commc’ns, LLC v. Limelight Networks, Inc.*, 611 F. Supp. 2d 572, 575 (E.D. Va. 2009) (quotation and citation omitted).

III. Analysis

Plaintiff argues that “the USPTO’s refusal to exercise discretion regarding and [its] denial of the USDA’s application for a second [Extension] of the ‘759 [P]atent was arbitrary and capricious and must be set aside.” (P. Mem. at 5.) Specifically, according to Plaintiff, the USPTO’s decision that it lacked discretion to consider the USDA’s untimely application, because § 156(d)(5)(C) uses “shall,” “fails for three reasons.” *Id.* First, “shall” is sometimes discretionary; second, the USPTO’s decision is “inconsistent with how the USPTO views Section 156 and how the law views the other timing provisions in federal patent law;” and third, “allowing the USPTO’s decision to stand will result in a harsh, absurd, and unfair result.” (P. Mem. at 5-6.)

Defendants counter Plaintiff’s statutory arguments regarding § 156(d)(5)(C), arguing “that Congress’s use of ‘shall’ renders a patent owner’s application to submit an application for a subsequent [Extension] in a timely fashion mandatory, and deprives the USPTO of discretion to entertain late-filed applications.” (D. Mem. at 15.) Defendants also

² Regardless of whether the statutory provision at issue is “substantive,” it is, at least, a procedural matter unique to patent law.

argue that, even if the language of § 156(d)(5)(C) is unclear, "the USPTO's interpretation must carry the day, because alternatively its formal regulations on this subject are entitled to binding . . . deference" under *Chevron USA, Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984).

The Court will address these arguments in turn.

A. Statutory Analysis

i. Language of § 156(d)(5)(C)

The issue before the Court concerns an interpretation of 35 U.S.C. § 156(d)(5)(C). To review, the statute provides that

[t]he owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. *Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.*

35 U.S.C. § 156(d)(5)(C) (emphasis added). The Court's analysis, then, begins with the language of § 156(d)(5)(C).

"As in any case of statutory construction, [the Court's] analysis begins with the language of the statute. . . . And where the statutory language provides a clear answer, it ends there as well." *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) (citation and internal quotation marks omitted).

The "preeminent canon of statutory interpretation requires [courts] to 'presume that the legislature says in a statute what it means and means in a statute what it says there.'" *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004) (quoting *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992)). The relevant statutory language is "[e]ach such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension." 35 U.S.C. § 156(d)(5)(C). As the parties agree that the USDA's second Extension application was not made during the relevant time period, the critical language for the Court's inquiry is "shall be made." *Id.* Specifically, can the USPTO consider an untimely application under that language.

"Shall" is not defined in the Patent Act. "When a word is not defined by statute, [courts] normally construe it in accord with its ordinary or natural meaning." *Smith v. United States*, 508 U.S. 223, 228 (1993). As for the ordinary or natural meaning of "shall," the American Heritage Dictionary defines "shall" as, among other things, "a requirement, or an obligation." American Heritage Dictionary of the English Language 1657 (3d ed. 1992). Black's Law Dictionary defines "shall," among other things, as "[h]as a duty to; more broadly,

is required to." Black's Law Dictionary 1407 (8th ed. 2004).³

These common usage definitions comport with courts' interpretations of the term. "Use of the word 'shall' in a statute generally denotes the imperative." *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007); see also *National R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 109 (2002) ("'[S]hall' makes the act of filing a[n administrative] charge [for purposes of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. § 2000e to e17 ('Title VII')] within the specified time period mandatory."); *Holland v. Pardee Coal Co.*, 269 F.3d 424, 431 (4th Cir. 2001) (noting that "the word 'shall,' when used in a statutory context, is generally construed to be mandatory). Thus, as one would expect, in both common and statutory usage, "shall" generally means a mandatory requirement or obligation.

In the proper context, however, "shall" may be permissive. "[W]e recognize that the context of a particular usage may at times require the construction of 'may' as mandatory or 'shall' as permissive." *LO Shippers Action Committee v. Interstate Commerce Comm'n*, 857 F.2d 802, 806 (D.C. Cir. 1988) (citing *United Hosp. Center, Inc. v. Richardson*, 757 F.2d 1445 (4th Cir. 1985)). Thus, regardless of the general meaning of "shall," it can sometimes be permissive, for example

³ Black's Law Dictionary further states that this meaning of "shall" is "the mandatory sense that drafters typically intend" and is the "[o]nly sense . . . acceptable under strict standards of drafting." *Id.*

when used in the clause "shall in its discretion." See *Trumbell Invs., Ltd. v. Wachovia Bank, N.A.*, 436 F.3d 443, 447 (4th Cir. 2006). But, "no such modifying context is present here." *LO Shippers*, 857 F.2d at 806.

The relevant language provides that "[e]ach such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension." 35 U.S.C. § 156(d)(5)(C). This language is unqualified. The application "shall be made" in the relevant period, full stop. Without any qualifying language, "[n]othing in the language of the statute states or suggests that the word 'shall' does not mean exactly what it says." *Merck*, 482 F.3d at 1322. Thus, "shall" has its ordinary meaning denoting a mandatory requirement or obligation.

ii. The Federal Circuit's *Merck* Decision

This reading is supported by the Federal Circuit's reading of "shall" in § 156(a). In *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317 (Fed. Cir. 2007), the Court read "shall" in § 156(a) as "the imperative." 482 F.3d at 1322. Though not a construction of § 156(d)(5)(C), "identical words used in different parts of the same statute are . . . presumed to have the same meaning." *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005). This canon of statutory construction, thus, supports reading "shall" in § 156(d)(5)(C) under its ordinary meaning.

In response to *Merck & Co.*, Plaintiff argues that "shall" in § 156(a) means something different than "shall" in § 156(d)(5)(C). (Plaintiff's Reply ("P. Reply") [Dkt. 17] at 11.) Plaintiff, however, has provided "no plausible argument that these terms mean something different" in the two sections. *IBP, Inc.*, 546 U.S. at 33. Plaintiff argues that because "shall" in § 156(d)(5)(C) is directed at the patent holder and not at the USPTO, § 156(d)(5)(C) is permissive. (P. Reply at 11.) Plaintiff also argues that § 156's remedial purpose leads to "shall" being read as permissive. The Court addresses both of those arguments below and finds that neither alters the meaning of "shall" from its common usage.

iii. USPTO Discretion

That "shall" in § 156(d)(5)(C) has its ordinary meaning does not end the inquiry. That mandatory requirement or obligation applies to the *applicant* for the Extension, and *not* the USPTO. That is, § 156(d)(5)(C) speaks to when a patent holder must file an application for an Extension, and does *not*, by its terms, address anything the USPTO must do. Put simply, saying that Plaintiff had a mandatory requirement or obligation to file its application within a certain period does not, in and of itself, address whether the USPTO had discretion to consider a tardy application. Thus, the Court turns to whether §

156(d)(5)(C) speaks to the USPTO's discretion, independent of imposing a mandatory obligation on Plaintiff.

On this front, § 156(d)(5)(C) is silent. Nothing in that statute, or in § 156 generally, answers the question of whether the USPTO has discretion to consider a tardy application under § 156(d)(5)(C). But, as Plaintiff argues, at least 10 other provisions of the Patent Act expressly grant the USPTO with discretion when administering time periods or deadlines. (Mem. at 14-15 (citing 35 U.S.C. §§ 41(b),(c)(1), 111(a)(4), 119(b)(2), (e)(1), 122(b)(2)(B)(iii), 133, 151, 184, 185, 364(b), 371(d)).) For example, 35 U.S.C. § 122(b)(2)(B)(iii) states that "[a] failure of the applicant to provide . . . notice within the prescribed period *shall* result in the application being regarded as abandoned, *unless* it is shown to the satisfaction of the Director that the delay in submitting the notice was unintentional." (emphasis added). The remaining provisions cited by Plaintiff are substantially similar in structure: a requirement on the patent holder or prospective holder, followed by an express grant to the USPTO of discretion to disregard the applicable requirement in certain instances if the requirement was not properly satisfied. Plaintiff argues that these provisions illustrate that the "USPTO's interpretation of [§ 156(d)(5)(C)] is inconsistent with the significant majority of all of the other similar timing

provisions of the patent law." (Mem. at 14.) The Court considers these other provisions and comes to a different conclusion.

The Supreme Court has stated that when "Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (citation omitted). The provisions of the Patent Law cited above serve the same function as § 156(d)(5)(C), but expressly grant the USPTO with discretion to disregard a failure to satisfy the provisions' respective requirements. Thus, following the *Russello* presumption, Congress acted intentionally and purposely in *not* granting that discretion in § 156(d)(5)(C).

Russello does not necessarily compel a reading in every case. As the Supreme Court has cautioned, "[t]he [*Russello*] presumption loses some of its force when the sections in question are dissimilar and scattered at distant points of a lengthy and complex enactment." *United States v. Granderson*, 511 U.S. 39, 63 (1994) (Kennedy, J., concurring). And, "[t]he *Russello* presumption . . . grows weaker with each difference in the formulation of the provisions under inspection." *City of*

Columbus v. Ours Garage & Wrecker Service, Inc., 536 U.S. 424, 435-36 (2002).

These caveats do not alter *Russello's* application here, however, as the sections at issue are neither dissimilar nor different in formulation. Indeed, for present purposes--whether the USPTO has discretion to disregard a patent holder or applicant's failure to comply with requirements set forth in the Patent Act in considering whether to grant that holder or applicant the benefit sought--they are identical. When provisions of the same statute (the Patent Act) serve identical purposes (setting forth requirements on patent holders or applicants), and 10 provisions expressly provide discretion to the USPTO to excuse noncompliance with the requirements but § 156(d)(5)(C) does not, the Court thinks *Russello* a reasonable tool of construction. Either Congress "act[ed] intentionally and purposely in the disparate inclusion or exclusion," *Russello*, 464 U.S. at 23, of the discretion-granting language, or it simply forgot to add the language. The Court will presume the former, particularly viewed in light of the plain meaning of "shall," as addressed above, and in light of the canon of statutory construction against superfluity.

iv. Superfluity

Another well-settled canon of statutory construction is that "against interpreting any statutory provision in a

manner that would render another provision superfluous." *Bilski v. Kappos*, 130 S. Ct. 3218, 3228 (2010) (internal citations omitted). As addressed above, 10 provisions cited by Plaintiff expressly grant the USPTO discretion. If, as in Plaintiff's reading of § 156(d)(5)(C), the USPTO has discretion regardless of the mandatory requirement placed on the patent holder (to file an application within a certain time period, for instance) and without the statute's granting discretion, then Congress would not have needed to provide for that discretion in the other provisions of the Patent Act cited above. Thus, all of that discretionary language would be unneeded and superfluous. Avoiding superfluity, however, is "a cardinal principle" of statutory construction. *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001). Thus, the Court will not construe § 156(d)(5)(C) in a manner to render the discretionary language expressly set forth in 35 U.S.C. §§ 41(b),(c)(1), 111(a)(4), 119(b)(2), (e)(1), 122(b)(2)(B)(iii), 133, 151, 184, 185, 364(b), and 371(d) as mere surplusage.⁴

v. *French v. Edwards*

Plaintiff argues that under the reasoning of *French v. Edwards*, 80 U.S. (13 Wall.) 506 (1872), and its progeny, § 156(d)(5)(C) is a "directory," not "mandatory," statute "and should be construed to confer discretion on the USPTO to accept

⁴ Because these provisions expressly provide for discretion, Plaintiff's argument is unavailing that the USPTO's interpretation of § 156(d)(5)(C) is inconsistent with these very timing provisions. (P. Mem. at 12, 14-15.)

applications outside the statutory window but before the patent expires." (P. Reply at 6.) Defendants counter that *French* and cases following it are "applied only to a very specific subset of timing provisions that utilize the term 'shall'--those that prescribe a timeframe within which a government official must carry out a ministerial duty." (Defendants' Reply ("D. Reply") [Dkt. 18] at 7.)

French, by its terms, addressed "statutory [provisions] intended for the guide of *officers in the conduct of business devolved upon them*, which do not limit their power or render its exercise in disregard of the requisitions ineffectual." *French*, 80 U.S. at 511 (emphasis added). The Supreme Court's later use of *French* reinforces its limited application. For example, in *United States v. Montalvo-Murillo*, 495 U.S. 711 (1990), a case addressing a statutory provisions stating that a "hearing shall be held immediately upon [a] person's first appearance before [a] judicial officer," *id.* at 714, the Court "h[e]ld that a failure to comply with the first appearance requirement does not defeat the Government's authority to seek detention of the person charged." *Id.* at 717. In so holding, the Court "reject[ed] the contention that if there has been a deviation from the time limits of the statute, the hearing necessarily [wa]s not one conducted" pursuant to the relevant statutory provision. *Id.* Citing *French*, the *Montalvo-*

Murillo Court stated that "[t]here is no presumption or general rule that for every duty imposed upon . . . *the Government* . . . there must exist some corollary punitive sanction for departures or omissions, even if negligent." *Id.* (emphasis added). Similarly, in *Brock v. Pierce County*, 476 U.S. 253, 260 (1986), the Court reiterated "the 'great principle of public policy, applicable to all governments alike, which forbids that the public interests should be prejudiced by the negligence of *the officers or agents* to whose care they are confided.'" 476 U.S. at 260 (emphasis added) (quoting *United States v. Nashville, C. & St. L.R. Co.*, 118 U.S. 120, 125 (1886)).

The upshot of this line of reasoning is articulated in *French* itself. Where a mandatory duty is placed on the *government*, in the proper circumstances that otherwise mandatory duty may be relaxed. Or, as the Fourth Circuit has framed it, "as the Supreme Court has pronounced, statutory provisions imposing a mandatory duty on an agency to act before a specific date are not generally construed to remove the agency's power to act after that date." *Pardee Coal*, 269 F.3d at 431. That is not the situation here, however, where both the duty and the failure to comply with it fall on the patent holder, and not the USPTO. To be sure, *French* provides an example of where "shall" is not necessarily mandatory. But, it is a limited exception to the general rule and, as establishing a circumstance in which an

otherwise mandatory obligation may be viewed as permissive, one inapplicable here.

Ralpho v. Bell, 569 F.2d 607, (D.C. Cir. 1977), cited by Plaintiff, is not to the contrary. There, the D.C. Circuit stated that "[s]tatutes that, for guidance of a governmental official's discharge of duties, propose 'to secure order, system, and dispatch in proceedings' are usually construed as directory, whether or not worded in the imperative." *Ralpho v. Bell*, 569 F.2d 607, (D.C. Cir. 1977) (emphasis added) (citing *French*, 80 U.S. at 511). *Ralpho* is in line with *French*.

Plaintiff argues that § 156(d)(5)(C), as applied in this case, "does relate to government action," namely "whether the USPTO can disregard [the timing provisions of § 156(d)(5)(C)]." (P. Reply at 7 (emphasis in original).) Thus, it is a "regulation of and 'guidance of a governmental official's discharge of duties.'" *Id.* (citing *Ralpho*, 569 F.2d at 627.) But, § 156(d)(5)(C) expressly does *not* guide the USPTO's discharge of its duties, *only* a patent holder's, as stated above. As to the USPTO's, it is silent. The statute itself may "relate to" the USPTO, but only as much as *any* provision of the Patent Act does. The duty in § 156(d)(5)(C), however, expressly applies *only* to the patent holder. Because the "shall" in § 156(d)(5)(C) applies to the patent holder and not to the USPTO, the reasoning of *French* and its progeny is

inapplicable. Therefore, *French* does nothing to alter the Court's reading of § 156(d)(5)(C).

vi. § 156 as a Remedial Statute

Plaintiff also argues that interpreting "shall" in § 156(d)(5)(C) as mandatory is inconsistent with the remedial nature of the statute. (P. Mem. at 8.) It is well-settled that "remedial legislation . . . is to be given a liberal construction consistent with [its] overriding purpose." *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969). As stated by this Court, in a case cited by Plaintiff addressing a different provision in § 156, "Section 156 provides a remedy: an extended patent term to offset the loss of effective patent life during the period of regulatory review of a new drug product. The timing provision of § 156(d)(1) is an integral part of the mechanism Congress enacted to remedy this harm." *Medicines Co. v. Kappos*, 731 F. Supp. 2d 470, 478 (E.D. Va. 2010). This is certainly sound, and § 156 is a "remedial" statute. *Medicines Co.*, however, did not go as far as Plaintiff would have the Court go here. As Judge Hilton stated, "Courts have held that the rule in construing remedial statutes is that everything is to be done in advancement of the remedy *that can be done consistently with any fair construction that can be put upon [the statute].*" *Id.* (emphasis added). Thus, a liberal construction is a not a license to re-write the

statute. See, e.g., *United States v. Floyd*, 992 F.2d 498, 501 (5th Cir. 1993) (“[T]his command for liberal construction does not allow us to amend by interpretation.”); see also *Dupuis v. Cancer Screening Servs.*, No. Civ. 96-169, 1997 WL 97110, at *4 (D. Me. Feb. 13, 1997) (“Rules of liberal construction cannot properly be applied to rewrite a statute in order to alter what it actually says.”).

Here, § 156(d)(5)(C) is not merely a remedy provided to patent holders, but also a statute *placing a mandatory obligation* on them. Again, it does not grant the USPTO any discretion whatsoever. It would be one thing to read liberally § 156(d)(5)(C)’s timing provisions placed on the patent holders, but another thing entirely to then read into the statute discretion on the part of the USPTO that is not there. A liberal reading of “shall” in § 156(d)(5)(C) is not enough to get to where Plaintiff would have this Court go. The Court would also need to add language to the statute to add discretion where Congress stated none. The Court will not do so.

This Court’s application of the liberal-reading-of-a-remedial-statute rule in *Medicines Co.* is instructive. There, the Court addressed § 156(d)(1), which provides that to obtain an extension of a patent term a patent holder’s application “may only be submitted within the sixty-day period beginning on the date the product received permission” from the applicable

regulatory agency. *Id.* at 472. At issue was whether "date" in "beginning on the date" meant calendar day or business day, and "[t]he Court f[ound] the proper interpretation of § 156(d)(1) [wa]s a business day construction of the phrase 'beginning on the date.'" *Id.* at 482. In that context, it is perfectly reasonable that a liberal construction of the remedial § 156 leads to "business day." The Court's analysis in *Medicines Co.* also illustrates why this case is different. First, § 156(d)(5)(C), unlike undefined "date" in § 156(d)(1), is unambiguous--it is mandatory as to Plaintiff and does *not* grant discretion to the USPTO. Second, unlike *Medicines Co.*, which reasonably applied one of two alternative common definitions for a term, Plaintiff here is effectively asking the Court to re-write, or at least add, whole-cloth, language to § 156(d)(5)(C). Thus, even the remedial nature of § 156 does not counsel the reading Plaintiff seeks.

Plaintiff also argues that, like *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385 (1982), addressing the timing requirements for filing of administrative claims with the Equal Employment Opportunity Commission prior to bringing Title VII cases in courts, "the time period in [§ 156(d)(5)(C)] is non-jurisdictional, and therefore may be tolled or extended, as equity permits." (P. Reply at 6.) In *Zipes*, the Supreme Court ruled that 42 U.S.C. § 2000e-5(e), which requires that

administrative proceedings in Title VII cases "shall be filed within [180] days after the alleged unlawful employment practice occurred," "is not a jurisdictional prerequisite to suit in federal court, but a requirement that like a statute of limitations, is subject to waiver, estoppel, and equitable tolling." *Zipes*, 455 U.S. at 393. Because § 156(d)(5)(C) is similarly non-jurisdictional, however, does not mean that under *Zipes* its time period is also subject to waiver, estoppel, and equitable tolling. This is so because "administrative agencies . . . are creatures of statute, bound to the confines of the statute that created them, and lack the inherent equitable powers that courts possess." *U.S. Fidelity and Guar. Co. v. Lee Invs. LLC*, 641 F.3d 1126, 1135 (9th Cir. 2011) (citing *Int'l Union of Elec., Radio & Mach. Workers, AFL-CIO v. NLRB*, 502 F.2d 349, 354 n.* (D.C. Cir. 1974)). Thus, with no inherent equitable powers, such as tolling or estoppel, the USPTO cannot, as a court could, toll the timing requirement of § 156(d)(5)(C) based solely on the fact that it is non-jurisdictional.

vii. Harsh Result

Plaintiff also argues that reading "shall" in § 156(d)(5)(C) as mandatory would "yield a . . . harsh and absurd result." (P. Mem. at 17.) As the Fourth Circuit has noted, "[courts] are not required to apply statutory language when such an application 'results in an outcome that can truly be

characterized as absurd.'" *In re Jones*, 591 F.3d 308, 313 n.4 (4th Cir. 2010) (quoting *Hillman v. IRS*, 250 F.3d 228, 233 (4th Cir. 2001)). Reading § 156(d)(5)(C) as the Court does, however, does not "result[] in an outcome that can truly be characterized as absurd." *Id.* It is not "absurd" to read a statute stating that one "shall" do something within a specified time period as requiring that thing to be done within that period. Nor is it "absurd" to read a statute that does not provide for discretion as not providing discretion. As for the harshness of the reading, to the extent it is harsh, that, in and of itself, does not cause the Court to alter its reading. As this Court has stated, "[t]he harsh result reached in this Memorandum Opinion is mandated by the language of the applicable statutes." *Howard Florey Inst. v. Dudas*, No. 1:07cv778, 2008 WL 2674033, at *12 (E.D. Va. July 8, 2008) (O'Grady, J.).

* * *

For these reasons, the USPTO's reading of § 156(d)(5)(C) is not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and the Court will grant summary judgment for Defendants.

B. Chevron Deference

Even assuming that the language of § 156(d)(5)(C) did not compel the Court's result, there is an alternative basis for

granting summary judgment for Defendants. The USPTO has promulgated formal regulations concerning § 156(d)(5)(C) and the time period stated therein. 37 C.F.R. § 1.790, entitled "[i]nterim extension of patent term under 35 U.S.C. 156(d)(5)," states that "[e]ach subsequent application for interim extension *must be filed* during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension." 37 C.F.R. § 1.790(a) (emphasis added). By its terms, 37 C.F.R. § 1.790(a) renders § 156(d)(5)(C)'s time period mandatory.

In *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the Supreme Court established a framework for according deference to agency interpretations of a statute it is charged with administering. The Supreme Court explained that if Congress "has directly spoken to the precise question at issue" and its intent is clear, then the "court, as well as the agency, must give effect to [that] unambiguously expressed intent." *Id.* at 842-43. If, however, "the statute is silent or ambiguous with respect to the specific issue," then the court must defer to the agency's interpretation as long as it is "based on a permissible construction of the statute." *Id.* at 843.

Defendants argue that "the USPTO's interpretation must carry the day, because . . . its formal regulations on

[§ 156(d)(5)(C)] are entitled to binding *Chevron* deference." (D. Mem. at 26). Plaintiff argues that the USPTO's "construction is contrary to law and cannot be afforded [*Chevron*] deference." (P. Reply at 14.) Significantly, Plaintiff does not dispute that 37 C.F.R. § 1.790(a) itself is subject to *Chevron* deference.

Here, for the reasons stated above, the USPTO's interpretation of § 156(d)(5)(C) is entitled to *Chevron* deference. The USPTO's interpretation is "based on a *permissible* construction of the statute." *Chevron*, 467 U.S. at 843 (emphasis added). As the Federal Circuit has stated, "to uphold the agency's interpretation, the court need not conclude that it was the only permissible construction or even the construction the court would have reached on its own reading of the statute. The agency's interpretation must merely be 'reasonable.'" *Eastman Kodak Co. v. Bell & Howard Document Mgmt. Prods. Co.*, 994 F.2d 1569, 1571 (Fed. Cir. 1993) (citations omitted). The USPTO's interpretation was permissible and reasonable and, indeed, is the same construction that Court reaches. Thus, the USPTO is entitled to *Chevron* deference here.

Plaintiff argues that 37 C.F.R. § 1.790(a) "by itself—[does not] constitute the regulatory interpretation of § 156(d)(5)(C)." (P. Reply at 14.) Plaintiff cites 37 C.F.R. § 1.182, stating that "[a]ll situations *not specifically provided*

for in the regulations of this part will be decided in accordance with the merits of each situation," and 37 C.F.R. § 1.183, stating that "[i]n an extraordinary situation, when justice requires, any requirement of the regulations in this part *which is not a requirement of the statutes* may be suspended or waived." (P. Reply at 14) (emphases added). The Court disagrees.

37 C.F.R. § 1.790(a) states that "[e]ach subsequent application for interim extension *must be filed* during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension." (emphasis added). This regulation, by its terms, specifically provides for the situation here, namely whether filing an application during the prescribed time period is mandatory. 37 C.F.R. § 1.182, then, is not applicable. Similarly, the timeliness requirement in 37 C.F.R. § 1.790(a) *is* a requirement of § 156(d)(5)(C), for the reasons set forth above. Thus, 37 C.F.R. § 1.183 is also inapplicable. Contrary to Plaintiff's argument, 37 C.F.R. § 1.790(a) constitutes the USPTO's regulatory interpretation of § 156(d)(5)(C), and as stated, it is a permissible interpretation for purposes of *Chevron* and, thus, entitled to deference, providing an independent basis for granting summary judgment in favor of Defendants.

IV. Conclusion

For these reasons, the Court will deny Plaintiff's motion, [Dkt. 13], and will grant Defendants' motion, [Dkt. 15].

An appropriate Order will issue.

July 21, 2011
Alexandria, Virginia

/s/
James C. Cacheris
UNITED STATES DISTRICT COURT JUDGE